

Butler, Jennie C

From: Gross, Mary
Sent: Friday, August 09, 2002 3:38 PM
To: Butler, Jennie C
Subject: FW: HCA/Federation of American Hospitals Testimony for FDA's July 26th Bar Coding Public Meeting...
Importance: High

-----Original Message-----

From: Dan Boston [mailto:dboston@americashospitals.com]
Sent: Friday, July 12, 2002 4:56 PM
To: Mary Gross - FDA
Cc: Susan VanGelder; Josie Martin; Alicia Perry - HCA; Richard Coorsh; Warren Tardy; Jane Englebright; Frank Houser, M.; Jana Joustra
Subject: HCA/Federation of American Hospitals Testimony for FDA's July 26th Bar Coding Public Meeting...
Importance: High

Ms. Gross –

Good afternoon,

Please see the attached testimony for your upcoming bar coding public meeting at the NIH on July 26th. This testimony by Jane Englebright, Vice President – Quality at HCA, Inc., will be delivered on behalf of both HCA and the Federation of American Hospitals. Additionally, we are also attaching one of the three exhibits noted in Ms. Englebright's testimony. The other two will be forwarded to you ASAP, under separate cover(s).

In the mean time, if you have any questions or have any technical problems with these materials, please don't hesitate calling either Susan VanGelder or me at (202) 624-1500.

Take care, and have a good weekend.

Dan Boston
Vice President – Legislation & Political Affairs
Federation of American Hospitals
801 Pennsylvania Avenue, NW, Suite 245
Washington, DC 20004
(202) 624-1522 – direct
(202) 316-2146 – cell
(703) 837-9748 - home

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Statement of

**Jane Englebright, Vice President - Quality
HCA, Inc.**

**Testimony before
the Food & Drug Administration of the
Department of Health & Human Services on
Bar Code Label Requirements for Human
Drug Products & Biologicals**

National Institutes of Health, Washington, DC
Friday, July 26, 2002

Ladies and Gentlemen, my name is Jane Englebright, and I am Vice President of Quality for HCA, Inc. I am pleased to testify this morning on behalf of both HCA and the Federation of American Hospitals (FAH) on the FDA's proposed rule for the bar coding of drugs and biologicals.

HCA owns and operates approximately 200 hospitals and other healthcare facilities in 24 states, England and Switzerland. We are dedicated to providing healthcare services that meet each community's local healthcare needs.

The Federation is the national trade association representing the nation's privately-owned and managed community hospitals and health systems across the acute and post-acute spectrum. Federation member hospitals provide care for patients in both urban and rural America.

Overview

Medications that have a standardized bar code are an essential component of Patient Safety for America's health systems.

HCA made a decision in February 2000 to develop its first corporate-wide clinical initiative. The HCA Patient Safety Initiative was designed to establish a culture of patient safety in the 186 hospitals that comprise HCA in the U.S. The initial component of this initiative, "Improving Medication Practices", is designed to significantly reduce the risk of human error in the ordering and administering of medications in our hospital. We are accomplishing this by improving operational medication use and developing and deploying two technologies aimed at improving medication safety. One technology is an electronic order entry system for doctors to use in ordering medicines and procedures. The other is an electronic administration system for nurses to use when administering medications. This administration system must have bar-coded medicines.

"Electronic Medication Administration Record (eMAR) and Bar Coding" is the technology that would greatly benefit from federal standardization of bar coding related to medications and medical devices. The 186 HCA facilities are slated to be in full use of this technology by the end of 2005. Two HCA hospitals, Skyline Medical Center and Port St. Lucie Medical Center are using the technology today. Fifteen additional HCA facilities are in the eMAR and Bar Coding planning process with implementation scheduled in the next six months.

Background

Evidence-based literature states 2% of hospital admissions have preventable adverse drug events, 34% of these errors occur during the process of medication administration.^{1,2} According to these numbers, a hospital with 8,000 admissions per year would have more than fifty errors related to medication administration alone.

Literature also supports a 65-74% reduction in medication errors in United States hospitals when a bar coded medication administration system is utilized^{3,4}. The system should work in the following manner:

1. Each medication should be unit-dosed.
2. Each unit dose medication should be labeled with human readable information and a bar code that includes the medication's National Drug Code (NDC) number, lot number and expiration date.
3. All medication containers should be labeled with human readable information and a bar code that includes the medication's NDC number, lot number and expiration date.
4. Each patient identification armband should contain human readable information and a bar coded identification number.
5. The nurse scans each patient and each medication before administering. The computer verifies that the five rights of medication safety administration are met and gives the nurse a warning or a validation message.
 - Right Patient
 - Right Medication
 - Right Dose
 - Right Route
 - Right Time
6. Documenting in a computerized system will generate a Medication Administration Record (MAR) and a charge for the administered medication.

Issues

- **The healthcare industry is overdue a standardized, uniform bar code.**
 - Bar coding was invented in 1949. More than a million companies worldwide use bar coding symbols to identify consumer products.⁵
- Bar code standardization efforts were initiated 1983.
- The healthcare industry has been slow to adopt bar coding technologies due to:
 1. Lack of manufacturer-assigned medication codes on unit dose medications used by hospitals.
 2. Lack of agreement among manufacturers on standard bar code format, content or symbology.
 3. Hospital repackaging and bar coding medications add a new opportunity for error and increases costs by approximately \$0.15 per dose. (A 150-bed hospital typically dispenses 90,000 doses/month and would see a \$162,000 increase in operating expenses each year.)⁶
 4. Costs of re-engineering manufacturing processes are significant.
 5. Cost of scanning and equipment for each patient care area of the hospital approaches \$250,000 for a 150-bed hospital.⁷
 6. Because of these difficulties, only 1.1% of hospitals surveyed were using bar coding technology in 1999.⁸
- Manufacturer accountability in bar coding allows costs to be distributed throughout healthcare systems and eases the burden of every individual hospital incurring costs for a duplicative process.

Recommendation

FDA regulation should require pharmaceutical manufacturers to label all medications, including unit dose medications, with both human readable and bar coded distinguishing information. Each dose should have a **single bar code** including NDC, lot number and expiration date. If accomplishing the task of bar coding medications results in a need to establish incremental steps, NDC number is the minimal amount of information needed to move forward. The overall plan should contain the expectation of NDC, lot number and expiration date as a final product.

Additional recommendations include ensuring:

1. Bar code print density is designed to provide reliable readability;
2. Reduced Space Symbolology (RSS) is the standard symbology chosen in order to provide the most cost efficient option for scanner selection and purchase; and
3. Food and Drug Administration (FDA) approvals related to labeling changes are streamlined to allow incorporation of lot number and expiration date to be a reasonable task.

Conclusion

The development of a standard bar code provides uniformity and is a key step in ensuring quality Patient Care. Labeling at the manufacturer level provides the safest quality controlled bar coding atmosphere. Hospital level labeling presents problems related to state wholesaling laws and practices, staffing and quality control. Widespread labeling at the hospital level may present issues that have the potential to negatively impact patient safety.

Exhibits

1. Federation of American Hospitals Position Statement;
2. Federation of American Hospitals Letter of Support to the National Coordination Council for Medication Error Reporting and Prevention; and
3. HCA Medication Safety Toolbox.

Demonstration

HCA is prepared to share a one-minute enactment of eMAR and Bar Coding technology.

References

- 1 Bates DW, Spell N, Cullen D, et al. The Costs of Adverse Drug Events in Hospitalized Patients. *JAMA*. 1997;277:307-311.
- 2 Bates DW et al. Incidence of adverse drug events and potential adverse drug events. *JAMA* 1995;274:29-34.

- 3 Malcom B, Carlson RA, Tucker CL, And Wilette C: Veterans Affairs: Eliminating Medication Errors through Point of Care Devices. Technical Paper presented at 2000 HIMSS Conference.
- 4 Puckett F: Medication management component of a point of care information system. *Am J Health-Syst Pharm*. 1995;52:1305-1309.
- 5 Fishman Charles. The Killer App - Bar None. *Fast Company*; Aug 2001.
- 6 McKesson Data/Skyline Medical Center Data- internally provided to corporate HCA
- 7 Coyle G: The highs and lows of bar code administration. www.corhealth.com 2001
- 8 ASHP: National survey of pharmacy practice in acute care settings: dispensing and administration – 1999. *Am J Health-Syst Pharm* (October 1, 2000) 57:1759-1775.

Reducing Medication Errors

The Federation of American Hospitals (FAH) believes that patient safety and high quality patient care are two important industry goals. To that end, the Board of Directors has previously approved a set of general principles on patient safety. These principles, developed in conjunction with a coalition of almost 100 organizations, address the importance of an educating, non-punitive environment, that ensures strong confidentiality of data collected for patient safety reporting systems.

The principles below have been developed to address one of the most significant factors affecting patient safety—medication errors. Using these principles as guidance, FAH members are working actively toward effectively reducing medication errors in health care facilities.

Principles Approved by FAH Board 8-22-01

- *Instill an organizational commitment, as well as an individual sense of responsibility and duty to high quality patient care, by all health care personnel.*
- *Explicitly educate patients and their family members about their medications at the point of care and at the point medications are dispensed.*
- *Include medication safety in staff orientation and competency programs.*
- *Encourage utilization of innovative technologies such as standardized machine readable bar coding on single unit dose packaging and computerized physician order entry (CPOE).*
- *Have essential patient information readily available to those ordering, prescribing and dispensing medications. This includes diagnoses, allergies, lab values, and current medication regimens, including neutraceuticals.*
- *Prominently display patient-specific critical information, such as known drug allergies, on patients' records or on the patients' themselves using wrist bands, etc.*
- *Develop and use protocols for patients receiving chemotherapeutic agents and other highly toxic drugs or those with a narrow therapeutic range.*

- *Develop and use protocols for handling verbal orders, including a requirement to repeat all verbal orders for verification.*
- *Publicize and promote the awareness of look-alike and sound-alike medications.*
- *Use standardized prescription writing and prescribing rules; minimize, if not eliminate, abbreviations. Use preprinted orders when possible.*
- *Develop and use standardized processes for storing, prescribing and dispensing medications that includes processes for doublechecking the original order, calculation, appropriateness, patient information and actual medication administered.*
- *Standardize commonly used equipment within a facility.*
- *Ensure adequate staff education and training on the operation and use of devices and equipment used for medication administration.*
- *Limit the number of dosages and types of infusion pumps used for intravenous solutions.*
- *Remove dangerous products, such as concentrated potassium chloride injection and lidocaine 2 percent 50-ml vials, from patient care areas.*
- *In creating medication error detection and reporting systems, hospitals should foster an environment that is education-based and non-punitive. FAH members are striving to implement performance improvement systems that:*
 - *are timely, identify the root causes of errors, and lead to corrective actions so that errors are caught quickly, intervention is rapid, and future errors are minimized or eliminated;*
 - *protect patient, health care personnel, and provider confidentiality regarding all information on medication errors;*
 - *are driven by the objectives of enhancing learning and maximizing patient trust; and*
 - *foster, not frustrate, a supportive error reporting environment.*